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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,306	09/28/2005	Danila Valmori	LUD 5739 US (10201468)	6397

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EXAMINER	
YOUNG, HUGH PARKER	
ART UNIT	PAPER NUMBER
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,306	VALMORI ET AL.	
	Examiner	Art Unit	
	Hugh P. Young	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) HPY

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

This is the first Office action on application 10,523,306. There are twenty-five claims pending in the application, all of which are the subject of this restriction requirement.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-7, drawn to an isolated peptide chosen from SEQ ID NOS: 1-20, 22-25, 60-87, 96, 101-103 or 108, and compositions made therefrom. This is NOT an election of species, but rather, an election of a single invention under Section 121, 35 USC.

Group II, claims 8-13, drawn to a composition comprised of two isolated peptides, each chosen from SEQ ID NOS: 1-20, 22-25, 60-87, 96, 101-103 or 108. This is NOT an election of species, but rather, an election of a single invention under Section 121, 35 USC.

Group III, claims 14-21, drawn to nucleic acids encoding an isolated peptide chosen from SEQ ID NOS: 1-20, 22-25, 60-87, 96, 101-103 or 108, and a recombinant expression system for them. This is NOT an election of species, but rather, an election of a single invention under Section 121, 35 USC.

Group IV, claims 22-24, drawn to methods of treating cancer with compositions of isolated peptides chosen from SEQ ID NOS: 1-20, 22-25, 60-87, 96, 101-103 or 108. This is NOT an election of species, but rather, an election of a single invention under Section 121, 35 USC.

Group V, claim 25, drawn to methods of diagnosing pathological conditions by use of an isolated peptide chosen from SEQ ID NOS: 1-20, 22-25, 60-87, 96, 101-103 or 108. This is NOT an election of species, but rather, an election of a single invention under Section 121, 35 USC.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, there is no nexus between the five groups regarding the compositions of matter: Groups I, II, IV, and V are drawn to peptides comprised of amino acids or their use, whereas Group III is drawn to compositions of nucleic acids and their use.

There is no general inventive concept over the Groups, given that different compositions of matter are claimed, and the treatment methods of Group IV are not necessarily subsumed by the diagnostic results of the methods of Group V. Thus, Groups I-V lack a single general inventive concept and are patentably distinct.

3. Furthermore, MPEP Appendix B Lack of Unity states:
(d) Illustrations of Particular Situations. There are three particular situations for which the method for determining unity of invention contained in Rule 13.2 is explained in greater detail:
(i) combinations of different categories of claims;
(ii) so-called "Markush practice "; and
(iii) intermediate and final products.
Principles for the interpretation of the method contained in Rule 13.2, in the context of each of those situations are set out below. It is understood that the principles set out below are, in all instances, interpretations of and not exceptions to the requirements of Rule 13.2. Examples to assist in understanding the interpretation
on the three areas of special concern referred to in the preceding paragraph are set out
below.
(e) Combinations of Different Categories of Claims. The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:
(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or
(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or
(iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process, it being understood that a process is specially adapted for the manufacture of a product if it inherently results in the product and that an apparatus or means is specifically designed for carrying out a process if the contribution over the prior art of the apparatus or means corresponds to the

> contribution the process makes over the prior art. Thus, a process shall be considered to be specially adapted for the manufacture of a product if the claimed process inherently results in the claimed product with the technical relationship being present between the claimed product and claimed process. The words "specially adapted " are not intended to imply that the product could not also be manufactured by a different process. Also an apparatus or means shall be considered to be "specifically designed for carrying out " a claimed process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art. Consequently, it would not be sufficient that the apparatus or means is merely capable of being used in carrying out the claimed process. However, the expression "specifically designed " does not imply that the apparatus or means could not be used for carrying out another process, nor that the process could not be carried out using an alternative apparatus or means.

4. For these reasons, the claims were grouped as Group I having the first claimed product, the first claimed method of using (Group IV), and the Groups II, III and V are subsequent compositions or methods of using them for various other end results.

5. The Examiner has required election of a single invention above, as indicated by the Groups I-V. As indicated above, Applicant must choose one (1) peptide sequence per invention to be searched, which the exception of Group II, which claims the use of two (2) peptides. The claims, 1-13, 22-25, comprise peptides that differ in structure because the sequences provided in these claims comprise non-conservative amino acid substitutions. Thus, overlapping sequences have been selected for inventions I, II, IV and V and the peptide sequences in each of inventions I, II, IV and V are considered to be patentably distinct. If anyone of inventions I, II, IV and V is elected the elected invention will only be examined insofar as it pertains to the sequences listed therein. This is **not** a species election: Applicant has not disclosed a common structure of the peptides that is the core of any common function or property; thus the peptides, as a

group, do not comprise a genus of subtended species, but rather an assortment of unrelated compounds.

If sequences of the other fifty-seven inventions in each of the other 3 Groups comprising peptides happen to be found in the search of the selected invention, the examiner will rejoin the invention comprising the found sequence in accordance with *In re Ochiai*. Rejoinder is possible if Applicants provide a single and specific representative subsequence, and state that the sequences are **not patentably distinct**. Applicants are informed that if their specified sequence is found that all or a specified subset of sequences are obvious over that prior art sequence.

Similarly, the nucleic acids of Group III encoding peptides of SEQ ID NOS: 1-20, 22-25, 60-87, 96, 101-103 or 108 are patentably distinct because the peptides they encode differ in structure. See also the item above in regards the peptides claimed in Groups I, II, IV and V. Rejoinder of all or a specified subset of the sequences is possible if Applicants provide a single and specific representative subsequence found in all or a specified subset of the sequences for search, and state that all or a specified subset of the sequences are not patentably distinct. Applicants are informed that if their specified sequence is found that all or a specified subset of sequences are obvious over that prior art sequence.

6. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their

recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventorship

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

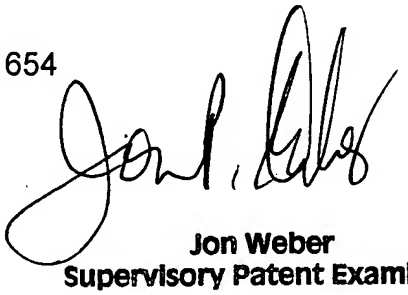
9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hugh P. Young whose telephone number is (571)-272-4988. The examiner can normally be reached on 8:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hugh P. Young Ph.D. GAU 1654



Jon Weber
Supervisory Patent Examiner